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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,544

11/14/2003

R. Steven Davidson

54275.8024.US01

7965

34055 7590 04/02/2007  
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EXAMINER

EBRAHIM, NABILA G

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

04/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/713,544	DAVIDSON, R. STEVEN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nabila G. Ebrahim	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, drawn to an edible film for the treatment of pharyngitis or cough, classified in class 424, subclass 48.
  - II. Claims 7-12, drawn to a multilayered edible film, classified in class 424, subclass 434,435.
  - III. Claims 13-18, drawn to a method of ameliorating a cough or pharyngitis using an edible film, classified in class 514, subclass 849.
  - IV. Claims 19-24, drawn to a method of ameliorating a cough or pharyngitis using a multilayered film, classified in class 514, subclass 849.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have materially different design since the ingredients can be comprised in a unilayer film, multiplayer film, a tablet, a multiplayer tablet, etc. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Art Unit: 1618

3. Inventions (I and II) and (III and IV) are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be practiced using any other film product for ameliorating symptoms of cough and pharyngitis such as Theraflu thin strips.

4. Inventions III and IV are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not obvious variants because it has the same effect on the same patient.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

Art Unit: 1618

because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. Claim 1 is generic to the following disclosed patentably distinct species: active ingredients selected from table 1, herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors. The species are independent or distinct because it comes from different sources and have different effects. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Applicant is also required to elect one active ingredient subspecies of each group of species (herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors) for example:

From the herbs: Adrographis paniculata Agrimony, bistort, blue gum tree, club moss, etc.

From tree plant sources: aloe, bee pollen, etc

To the end of the species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1618

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

7. Claim 7 is generic to the following disclosed patentably distinct species: active ingredients selected from table 1, herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors. The species are independent or distinct because it comes from different sources and have different effects. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Applicant is also required to elect one active ingredient subspecies of each group of species (herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors) for example:

From the herbs: Adrographis paniculata Agrimony, bistort, blue gum tree, club moss, etc.

From tree plant sources: aloe, bee pollen, etc

To the end of the species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1618

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

8. Claim 13 is generic to the following disclosed patentably distinct species: active ingredients selected from table 1, herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors. The species are independent or distinct because it comes from different sources and have different effects. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Applicant is also required to elect one active ingredient subspecies of each group of species (herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors) for example:

From the herbs: Adrographis paniculata Agrimony, bistort, blue gum tree, club moss, etc.

From tree plant sources: aloe, bee pollen, etc

To the end of the species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1618

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

9. Claim 19 is generic to the following disclosed patentably distinct species: active ingredients selected from table 1, herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors. The species are independent or distinct because it comes from different sources and have different effects. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Applicant is also required to elect one active ingredient subspecies of each group of species (herbs, tree and plant sources, vitamins and minerals, bacteria, essential oils and flavors) for example:

From the herbs: Adrographis paniculata Agrimony, bistort, blue gum tree, etc.

From tree plant sources: aloe, bee pollen, etc

To the end of the groups of species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Art Unit: 1618

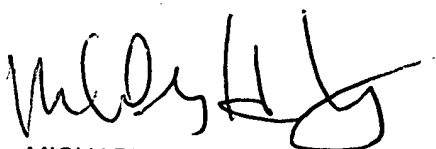
10. Because of the complex nature of the restriction requirement no telephone call was made to the Applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim  
3/9/07



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER